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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,193	09/19/2003	Andrew H. Segal	11111/2003G	6811

29933 7590 07/11/2008
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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,193	SEGAL ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-16 are pending. Claim 9 is withdrawn for being directed to a non-elected invention. Claims 1-8 and 10-16 are under examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-8 and 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoo.[1]

In response to the rejection, Applicant argues that the claimed invention is not anticipated by Hoo et al. Applicant argues that Hoo et al. does not teach the administration of both bounded and unbounded multifunctional molecule with cells, wherein the presence of unbounded multifunctional molecule with cells is an indispensable element of the claimed invention. Applicant also criticizes specific passages in the prior art cited by the Office.

Applicant's arguments have been considered, however, it is not found persuasive. Contrary to Applicant's assertion, Hoo et al. does teach the administration of both bounded and unbounded multifunctional molecule with cells. The Office directs Applicant's attention to Example II of Hoo et al. At the cited example, Hoo et al.

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[1] Hoo, W., U.S. Patent No. 5891432, published April 06, 1999.

administered unwashed cells expressing the bounded multifunctional molecule. Because Hoo et al. did not wash these cells to eliminate unbounded multifunctional molecules, Hoo et al. inherently administered both bounded and unbounded multifunctional molecules with cells. In the instant case, it is found that the procedure used by Hoo et al. to administer both bounded and unbounded multifunctional molecule with cells is the same as Applicant. Per Applicant's disclosure, Applicant teaches that the administration of unwashed cells expressing the bounded multifunctional molecule also includes unbounded multifunctional molecules. See pages 176-178 of Applicant's disclosure. In the instant case, while Applicant's arguments have been considered, and the fact that unbounded multifunctional molecules are indispensable element of the claimed invention, it remains that Hoo et al. teaches the claimed invention. Applicant is also reminded that the rejection is over the entire disclosure of the reference and not solely the cited passages. Thus, Applicant's criticism of cited passages made by the Office is not sufficient to invalidate the teachings of the cited prior art. In the instant case, it is clearly established by the Office that the claimed invention is anticipated by the cited prior art, Hoo et al.

The claims are directed to the administration of a composition to an animal to modulate an immune response. The composition comprises an antigen and a fusion polypeptide comprising i) a first amino acid sequence that comprises a cell-surface binding moiety and ii) a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein the antigen and the fusion polypeptide are bounded and unbounded together. Claim 2, which depends on claim 1, limits the

animal to a mammal, which is later limited to a human by claim 3. Claim 4, which depends on claim 1, clarifies that that the first and second amino acid sequences are joined to render a fusion polypeptide. Claims 5-6, which depend on claim 4, require the first amino acid to be N- and C-terminal to the second amino acid sequence, respectively. Claim 7, which depends on claim 1, limits the second amino acid sequence to a ligand for a cytokine receptor, which is limited to GM-CSF, the elected invention, by claim 8. Claim 10, which depends on claim 1, requires the antigen to be a tumor cell, a bacterial cell, a fungal cell, a cell of a parasite, a mammalian cell or an insect cell. Claim 11, which depends on claim 1, requires the antigen to be a pathogenic cell or virus. Claim 12, which depends on claim 1, requires the antigen to be an attenuated cell or virus. Claim 13, which depends on claim 1, requires the antigen to be a cell that is unable to divide. Claim 14, which depends on claim 1, requires the leukocyte to be an antigen presenting cell, which is specified as a professional antigen presenting cell by claim 15 and dendritic cell by claim 16.

Hoo teaches the administration of a composition to an animal to modulate an immune response. [Claims 13-24, in particular.] The composition of Hoo comprises an antigen and a fusion polypeptide. [Claims 1-12, in particular.] In the composition of Hoo, the antigen and the fusion polypeptide are bounded and unbounded together. The antigen that Hoo teaches includes a virus, a bacterial cell, fungal cell, a cell of a parasite, a mammalian cell, pathogenic and attenuated antigens, and a cell that is substantially unable to divide. [Lines 35-45, column 10, and columns 9-18, in particular.]

The first amino acid sequence in the fusion polypeptide of Hoo comprises the sequence to a membrane attachment domain, a cell-surface binding moiety. The second amino acid sequence in the fusion polypeptide of Hoo comprises the sequence of a ligand for a cell surface polypeptide of a leukocyte. Specifically, the ligand for a cell surface polypeptide of a leukocyte is a ligand for a cytokine receptor. In particular, the ligand for a cytokine receptor that Hoo et al. teaches is GM-CSF. [Example I, column 22, in particular.] The ligand for a cell surface polypeptide used by Hoo is a ligand for a ligand for a cell surface polypeptide of a leukocyte, wherein the leukocyte is dendritic cells, which is a professional antigen presenting cell. [Columns 1-2, in particular.] Hoo teaches that the first amino acid sequence can be N-terminal and C-terminal to the second amino acid sequence.

In the instant case, the composition of Hoo et al. is the same as the claimed invention. Therefore, the claimed invention is anticipated by Hoo.

Conclusion

4. No claims are allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Le/
Primary Examiner, Art Unit 1648

/E. L./